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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,599	12/02/2005	Sibaji Sarkar	701586-53012	6524

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EXAMINER	
JAGOE, DONNA A	

ART UNIT	PAPER NUMBER
1614	

MAIL DATE	DELIVERY MODE
06/12/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/537,599	SARKAR ET AL.	
	Examiner	Art Unit	
	Donna Jagoe	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 April 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *24-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/6/05 & 2/12/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group III, claims 24-27 in the reply filed on April 16, 2009 is acknowledged.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claims 24-27 are presented for examination.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 24, 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over DePetrillo et al. U.S. Patent Application Publication 2002/0115665 A1 (A4 from IDS dated 2/12/07)

DePetrillo et al. teach administration of calpain inhibitors (HIV protease inhibitors to patients that are exposed to calpain mediated physiological damage (see abstract) such as thrombotic platelet aggregation (paragraph 6). DePetrillo et al. teach Calpain inhibitors are administered after calpain-mediated physiological damage such as myocardial infarction or stroke or angina (paragraph 106) and teach that said damage includes thrombosis or thrombotic platelet aggregation (paragraph 113). DePetrillo et al. does not specifically recite "fibrinolysis" however, the doses administered in the instant case capable of promoting fibrinolysis are from 5 to 1000 mg (paragraph 103) which partially overlaps with the doses recited in the treatment of DePetrillo et al. from

300 to 2400 mg – (see claims 31-32 of the patent). As noted in *In re Best* (195 USPQ 430 (CCPA 1977)), and *In re Fitzgerald* (205 USPQ 594 (CCPA 1980)), the mere recitation of newly-discovered function or property, inherently possessed by things in prior art, does not cause claims drawn to those things to distinguish over prior art. In such a situation, the burden is shifted to the applicant to prove that subject matter shown to be in prior art does not possess characteristic relied on where it has reason to believe that functional limitation asserted to be critical for establishing novelty in claimed subject matter may be inherent characteristic of prior art; whether rejection is based on "inherency" under 35 U.S.C. 102, on "prima facie obviousness" under 35 U.S.C. 103, jointly or alternatively, burden of proof is same. Although DePetrillo et al. do not specifically recite lysis of the thrombosis or thrombotic platelet aggregation, the burden is shifted to Applicant to prove that the calpain-inhibitors of DePetrillo et al. do not promote fibrinolysis.

Regarding claim 27 drawn to a kit for promoting fibrinolysis comprising a compound of claim 24 and a pharmaceutically acceptable carrier, calpain inhibitors such HIV protease inhibitors ritonavir, saquinavir, indinavir, nelfinavir and amprenavir are known from the above recited reference (see claim 46). Given that DePetrillo et al teach calpain inhibition treats thrombotic platelet aggregation, it would have been *prima facie* obvious to one of ordinary skill in the art to enclose any of these agents in a vessel and include instructions as to how to administer the contents of the vessel for that purpose. Because the printed matter in the instructions has no functional relation with the substrate on which it appears, it does not distinguish appellant's claimed invention

over that the prior art recited supra. *See In re Gulack*, 703 F.2d 1381, 1385, 217 USPQ 401, 404 (Fed. Cir. 1983). Hence, the kit recited in instant claim 27 would have been *prima facie* obvious to one of ordinary skill in the art.

Claims 24, 25 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hisamichi et al. U.S. Patent No. 6,432,963 B1

Hisamichi et al. teach pyrimidine-5-carboxamide derivatives having Syk tyrosine kinase inhibition activity (column 1, lines 5-8) for treatment of diseases in which platelet agglutination takes part such as thrombosis and the like (column 13, lines 36-38). It does not specifically teach promotion of fibrinolysis, however, the doses administered in the instant case capable of promoting fibrinolysis are from about 0.5 to about 100 mg/kg of body weight per day (paragraph 102). This dose partially overlaps with the doses recited in the treatment of Hisamichi et al. who teaches from about 0.001 to 100 mg/kg (column 16, lines 27-30). As noted in *In re Best* (195 USPQ 430 (CCPA 1977)), and *In re Fitzgerald* (205 USPQ 594 (CCPA 1980)), the mere recitation of newly-discovered function or property, inherently possessed by things in prior art, does not cause claims drawn to those things to distinguish over prior art. In such a situation, the burden is shifted to the applicant to prove that subject matter shown to be in prior art does not possess characteristic relied on where it has reason to believe that functional limitation asserted to be critical for establishing novelty in claimed subject matter may be inherent characteristic of prior art; whether rejection is based on "inherency" under 35 U.S.C. 102, on "prima facie obviousness" under 35 U.S.C. 103, jointly or alternatively, burden

of proof is same. Although Hisamichi et al. do not specifically recite lysis of the thrombosis, the burden is shifted to Applicant to prove that the Syk kinase inhibitors of Hisamichi et al. do not promote fibrinolysis.

Regarding claim 27 drawn to a kit for promoting fibrinolysis comprising a compound of claim 24 and a pharmaceutically acceptable carrier, Syk kinase inhibitors such the pyrimidine-5-carboxamide derivatives are known from the above recited reference. Given that Hisamichi et al teach Syk kinase inhibition treats thrombosis, it would have been *prima facie* obvious to one of ordinary skill in the art to enclose any of these agents in a vessel and include instructions as to how to administer the contents of the vessel for that purpose. Because the printed matter in the instructions has no functional relation with the substrate on which it appears, it does not distinguish appellant's claimed invention over that the prior art recited supra. *See In re Gulack*, 703 F.2d 1381, 1385, 217 USPQ 401, 404 (Fed. Cir. 1983). Hence, the kit recited in instant claim 27 would have been *prima facie* obvious to one of ordinary skill in the art.

Thus the claims fail to patentably distinguish over the state of the art as represented by the cited references.

Accordingly, for the above reasons, the claims are deemed properly rejected and none are allowed.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna Jagoe whose telephone number is (571) 272-

0576. The examiner can normally be reached on Monday through Friday from 8:00 A.M. - 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Donna Jagoe /D. J./
Examiner
Art Unit 1614

June 5, 2009

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614